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(54) Abstract Title
Implantable pump

(57) A pump system for use in the treatment of ascites. A saphenous vein is severed and connected into the peritoneal cavity. Ascitic fluid which has accumulated in the peritoneum cavity is pumped out of the cavity and into the vascular system via the anastomosed saphenous vein. An implantable pump situated in the fluid flow path increases the efficiency of evacuation of the peritoneum. Provision is made for accurately controlling the pump system with the aid of pressure sensors located in the flow path. Cancerous cells within the fluid can be filtered out and thus prevented from circulating into the vascular system, and a reservoir compartment can be provided for needle aspiration thereof. The pump may be monitored and/or powered remotely.

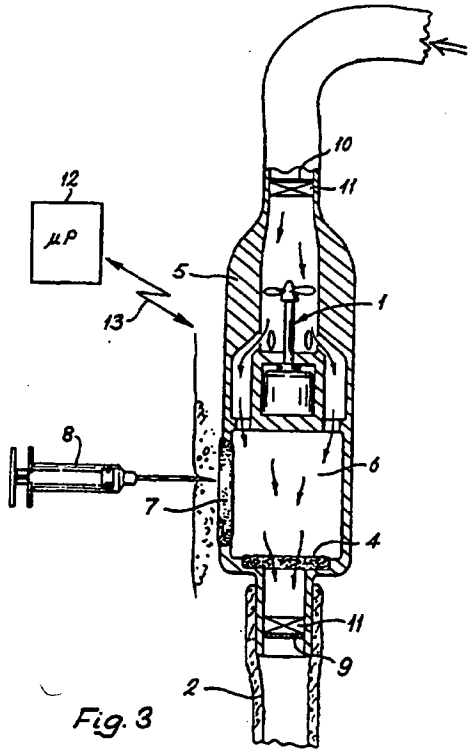

Fig. 3

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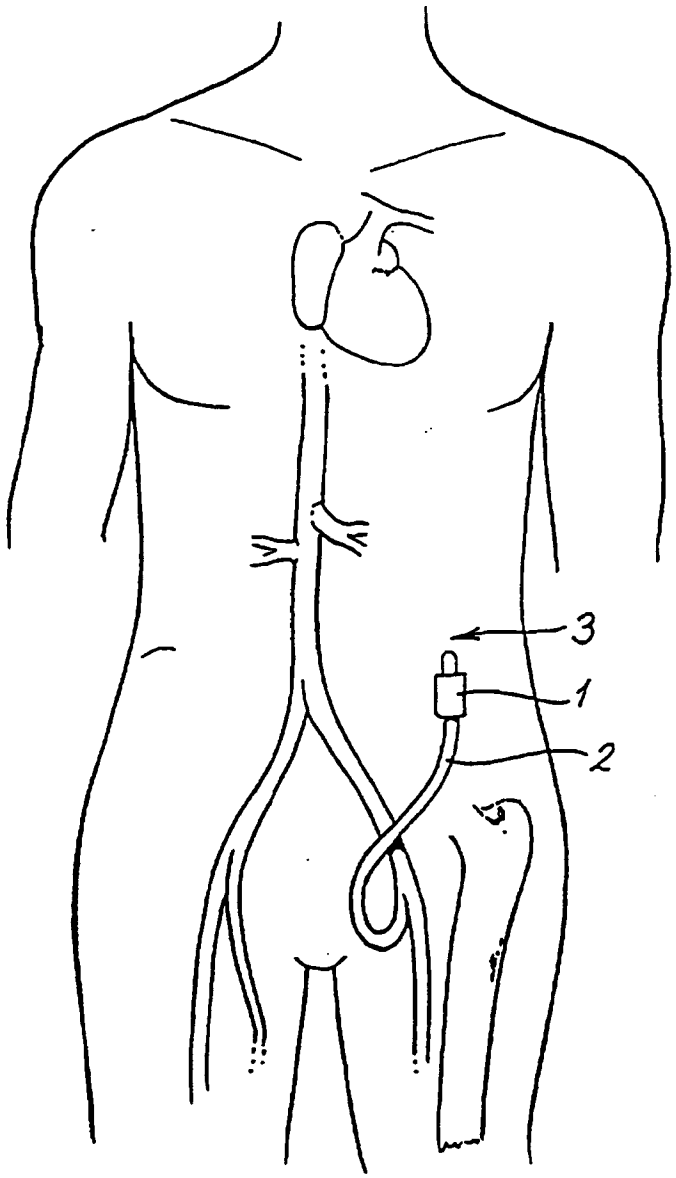

Fig. 1

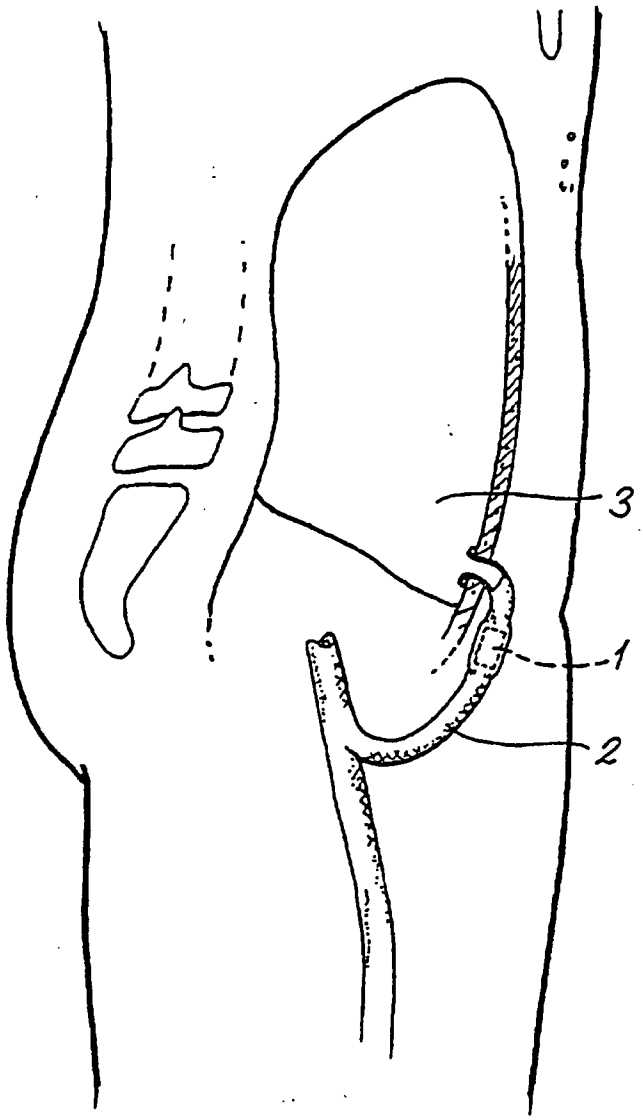

Fig. 2

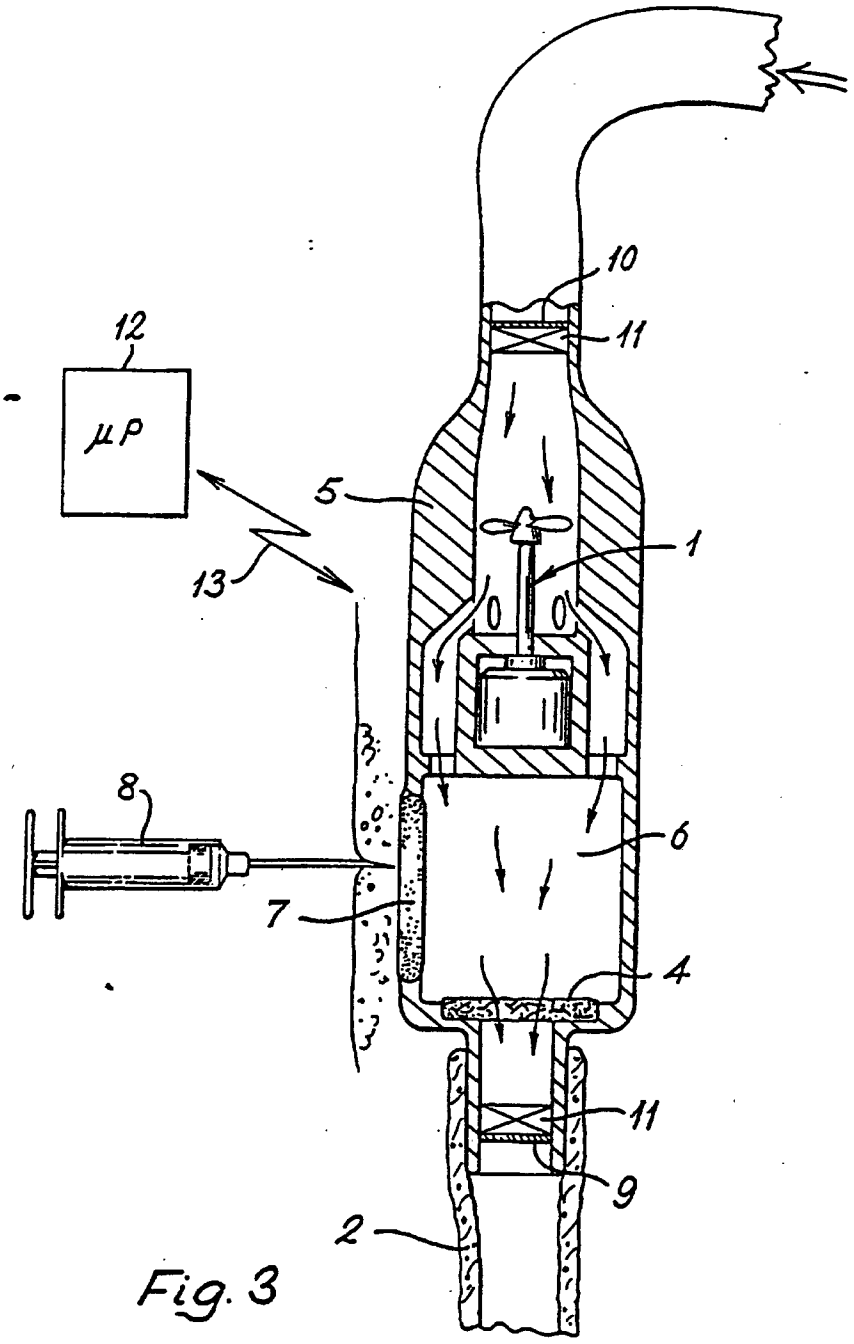

Fig. 3

IMPLANTABLE PUMP FOR ASCITES TREATMENT

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This invention relates to the treatment of ascites in clinical or veterinary situations, and is of particular relevance in the advanced stages of that condition.

Ascites is a clinical condition characterised by the accumulation of ascitic fluid (water rich in albumin) in the peritoneal cavity. Such a condition can result from widespread tumour in the abdomen, blockage of the portal vein and/or cirrhosis of the liver. It causes abdominal swelling and discomfort for the subject. In addition it can lead to loss of albumin, renal failure and difficulty in breathing.

In the earlier stages ascites can be treated with diuretics. Advanced stages, however, are difficult to treat and become resistant to such therapy. In such cases the condition may be treated with peritoneo-jugular shunts comprising synthetic tubes through which the ascitic fluid can be drained from the peritoneal cavity to the jugular vein (Denver and Leveen shunt methods).

The results of this conventional treatment of ascites have so far proved poor as they are not particularly effective in emptying the peritoneal cavity of ascitic fluid. Medical measures which have also been applied in cases of this kind include repeated paracentesis (i.e. drainage of ascitic fluid to the exterior of the body) and albumin infusion. Again, the results of these treatments have been less than ideal.

The invention aims to improve the existing situation and provide a more effective treatment for the condition of ascites. To this end the inventor has devised a new operation in which the peritoneal cavity is connected into the patient's systematic circulation via the reversed saphenous vein and thence to the femoral vein.

According to a first aspect of the invention there is provided an implantable pump system for use in the transfer of ascitic fluid from the peritoneal cavity to the vascular system comprising an implantable pump for insertion in the fluid flow path formed between a severed and reversed saphenous vein and the peritoneal cavity; means for driving the pump, such that in use it causes the pump to evacuate ascitic fluid contained within the peritoneal cavity. The use of a pump greatly increases the efficiency of the transfer of ascitic fluid out of the peritoneal cavity over simple shunt arrangements. Various advantageous aspects are defined in the subclaims; for example,

the pump may be dimensioned such that it can be implanted within the saphenous vein itself, thus reducing the degree of surgical invasion to a minimum. Where the build-up of ascitic fluid is due to a cancerous condition, a filter can be provided to filter out undesirable cells and prevent them from being transferred to the vascular system. The cancer cells can be conveniently collected by providing a reservoir compartment upstream of the filter. The reservoir compartment can be provided with a flexible membrane so the unwanted cells can be aspirated. This also allows monoclonal antibodies to be introduced into the compartment, to attack the cancer cells. The operation of the pump can be controlled by means of sensors, allowing the system parameters to be finely tuned to the needs of the patient.

According to another aspect of the invention there is provided a method for the treatment of ascites comprising pumping ascitic fluid from the peritoneal cavity into a saphenous vein. According to a further aspect of the invention, there is provided a method of transferring ascitic fluid from the peritoneal cavity to the vascular system comprising severing a saphenous vein; reversing the severed vein; implanting an intravascular pump in the reversed saphenous vein; implanting the reversed saphenous vein in the peritoneal cavity; and driving the pump to evacuate ascitic fluid from the peritoneal cavity into the saphenous vein.

The reversal of the saphenous vein is a relatively simple surgical procedure and use of this vein reduces problems of thrombosis often encountered with larger veins such as the jugular. Since ascitic patients are often weakened and do not tolerate prolonged surgery, simplification of any surgical procedure which provides their relief is particularly beneficial.

For a better understanding of the invention and to show how the same may be carried into effect, it will now be described in further detail with reference to specific non-limiting embodiments. Reference is made to the accompanying figures, in which;

Figure 1 is a diagram of the human vascular system showing the reversed saphenous vein routed to the peritoneum.

Figure 2 is a side view showing the reversed saphenous vein and implantable pump.

Figure 3 is a detail view of the arrangement of the pump.

Referring first to Figures 1 and 2, the drainage system comprises an implantable pump (1) which is located either between the end of the severed saphenous vein (2) and the peritoneal cavity (3) (Figure 1) or intravascularly, that is, within the saphenous vein, and the free end of the vein is located in the peritoneal cavity (Figure 2).

The patient is treated in the following manner. The saphenous vein is severed and the portion of the vein which is still connected to the femoral vein is reverted and anastomosed to the peritoneal cavity. The other end of the vein remains in situ and is blocked by suitable surgical means. The pump may be dimensioned to fit inside the free end of the saphenous vein (Figure 2), which is then inserted into the peritoneal cavity. Alternatively, the pump may be located externally of the saphenous vein with one side of the pump (efferent) connected to the end of the saphenous vein and the other side (afferent) connected either directly or via a tube to the peritoneal cavity (Figure 3). The pump can be placed either within the peritoneal cavity itself or within the subcutaneous region in the vicinity of the peritoneal wall. The latter is advantageous where the need for future access to the pump arrangement is envisaged.

As mentioned earlier, the condition of ascites is common in patients suffering from certain forms of cancer. In such cases the ascitic fluid may contain cancerous or other undesirable cells, and the transfer of fluid from the peritoneal cavity to the saphenous vein will inevitably lead to dissemination of such cells throughout the vascular system. This can be avoided by incorporating a filter (4) within the pump housing (5), preferably downstream of the pump (1), as illustrated in Figure 3. Preferably there is a reservoir compartment (6) between the pump and filter to allow space for unwanted cells. The pump and filter may be manufactured as an integrated unit in a single housing as in Figure 3 or may be provided in a separate housing connected in line with the pump via a tube. Provision may be made for aspirating the unwanted cells. This can be achieved by situating the compartment subcutaneously and providing a flexible membrane (7) which can be aspirated with a syringe needle (8). Alternatively a small tube can be fed from the reservoir compartment to the outside of the body to allow evacuation of the compartment as appropriate. Monoclonal antibodies directed to cancer-associated antigens may also be injected into the compartment.

The pump is preferably of the zero external displacement type. If intended for insertion within vein itself, the pump will have a width in the order of several mm. The capacity of the pump may be anything from ~ 2 litres per hour to ~2 litres per day, in order to cope with extreme cases of ascites, but in general will evacuate the peritoneal cavity at a rate of up to 2 litres per day. The pump may be empowered for continuous low level operation, may be controlled manually, or may be automatically controlled to operate intermittently, with pressure sensors (9) (10) connected to a control system (12) being used to monitor the pump and control it as necessary. A single sensor downstream or upstream of the pump may suffice, or alternatively both downstream and upstream sensors can be provided, where control of the pump is critical. The control may be provided in the form of a dedicated microprocessor. The control system will control the pump to cease pumping when the efferent pressure (i.e. in the vein) as measured by a first sensor (9) downstream of the pump rises above a predetermined level (~ 30mm Hg) to prevent damage to the vein and/or when the afferent pressure as measured by a second sensor (10) upstream of the pump falls below a predetermined level (~ 5-10 mm Hg), to prevent cavitation of the pump and power wastage. If the afferent pressure drops suddenly, indicating a haemorrhage in the system, an alarm can be signalled. Suitable valves (11) can be provided in the pump to prevent reverse flow through the system when the pump is not in operation although this should not generally be necessary if the sapheno-femoral valve at the junction of the saphenous and femoral veins is intact.

The pump and sensor/control circuitry may either be empowered by conventional wire means or by telemetric means (13). Since the pump will generally be situated within 20cm of the surface of the body, the power requirements for telemetric control will be reasonable. Telemetric control also allows the surgeon to adjust the pump parameters (duty cycle, pressure thresholds etc.) dynamically to best suit the condition of the patient. Where conventional wire means are used, all components of the system including the battery may be implanted subcutaneously. In certain circumstances a simple externally activated mechanical pump, actuated for instance by external magnetic means, may suffice.

CLAIMS

1. An implantable pump system for use in the transfer of ascitic fluid from the peritoneal cavity to the vascular system comprising :
an implantable pump for insertion in the fluid flow path formed between a severed and reversed saphenous vein and the peritoneal cavity;
means for driving the pump, such that in use it causes the pump to evacuate ascitic fluid contained within the peritoneal cavity.

2. An implantable pump system according to claim 1 wherein the pump is dimensioned such that it can be implanted in the saphenous vein.

3. An implantable pump system according to claim 1 or 2 further comprising filter means to prevent transfer of undesirable cells into the vascular system.

4. An implantable pump system according to any of claim 1 to 3 further comprising a first pressure sensor located downstream of the pump.

5. An implantable pump system according to any preceding claim further comprising a second pressure sensor located upstream of the pump.

6. An implantable pump system according to claim 4 or 5 further comprising a control means, operable in use in conjunction with said first and/or second sensors so as to control the action of the pump.

7. An implantable pump system according to claim 6 wherein the control means is arranged to activate the pump when the afferent pressure falls below a predetermined level.

8. An implantable pump system according to claim 6 or 7 wherein the control means is arranged to stop pumping when the efferent pressure rises above a predetermined level.

9. An implantable pump system according to claim 3 further comprising a reservoir compartment located between the pump and the filter for collection of said undesirable cells.

10. An implantable pump system according to claim 9 wherein the reservoir compartment includes a flexible membrane provided for needle aspiration of said cells from said compartment and/or introduction of monoclonal antibodies into said compartment.

11. An implantable pump system according to claims 9 or 10 wherein the pump, reservoir compartment and filter are integrated in a single housing.

12. An implantable pump system according to any preceding claim further comprising telemetric means for controlling and/or empowering said pump.

13. A method of transferring ascitic fluid from the peritoneal cavity to the vascular system comprising:
severing a saphenous vein;
reversing the portion of severed vein closest to the femoral vein;
implanting an intravascular pump in the reversed saphenous vein;
implanting the reversed saphenous vein in the peritoneal cavity;
driving the pump to evacuate ascitic fluid from the peritoneal cavity into the saphenous vein.

14. A method for the treatment of ascites comprising pumping ascitic fluid from the peritoneal cavity into a saphenous vein.

15. A method according to claim 14 wherein the saphenous vein is severed and anastomosed to the peritoneal cavity, and wherein said pumping is performed using an implanted pump.

16. A method according to claim 15 wherein said pump is implanted in the saphenous vein.

17. A method according to claim 15 wherein the pump is connected between said vein and the peritoneal cavity.

18. Use of an implantable pump in the manufacture of a product for application in surgery to treat the condition of ascites, whereby the pump is incorporated in said product.

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Claims searched: 1-12 **Date of search:** 4 October 2000

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Search Report under Section 17

Databases searched:

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Int Cl (Ed.7): A61M 1/12, A61M 27/00

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 2 055 294 A	(HAKIM) See page 2 line 25-70 & Figures	1
X	WO 83/01387 A1	(LeVEEN) See figure 3 & page 8 line 2-32	1
X	US 4 850 955	(NEWKIRK) See column 7 line 58 - column 8 line 50	1
X	US 4 725 207	(BUCHWALD) See figures & column 3 line 1-column 4 line 38; column 6 line 26-65	1 & 4-6
X	US 4 657 530	(BUCHWALD) See column 4 line 9-62	1
X	US 4 553 956	(MULLER) See column 3 line 61-column 4 line 27; column 5 line 25-44	1
X	US 4 240 434	(NEWKIRK) See Figures & claim 1	1

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